Proposed Maximum Residue Limit PMRL2017-15

# Isofetamid

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on various commodities to the product label of Isofetamid 400SC Fungicide, containing technical grade isofetamid, is acceptable. The specific uses approved in Canada are detailed on the label of Isofetamid 400SC Fungicide, *Pest Control Products Act* Registration Number 31555.

The evaluation of this isofetamid application indicated that the end-use product has value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for isofetamid is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

The proposed MRLs, to be added to the MRLs already established for isofetamid, are as follows.

**Table 1 Proposed Maximum Residue Limits for Isofetamid**

| Common Name | Residue Definition | MRL (ppm)[1] | Food Commodity |
|---|---|---|---|
| Isofetamid | *N*-[1,1-dimethyl-2-[2-methyl-4-(1-methylethoxy)phenyl]-2-oxoethyl]-3-methyl-2-thiophenecarboxamide | 10 | Small fruits vine climbing, except grape (crop subgroup 13-07E)[2] |
| | | 5.0 | Bushberries (crop subgroup13-07B) |
| | | 4.0 | Cherries (crop subgroup 12-09A); peaches (crop subgroup 12-09B); caneberries (crop subgroup 13-07A) |
| | | 1.5 | Dried prune plums |
| | | 0.8 | Plums (crop subgroup 12-09C) |
| | | 0.6 | Apples; edible-podded legume vegetables (crop subgroup 6A, except pea (Pisum spp.), including dwarf pea, edible-podded pea, snow pea, sugar snap pea, and pigeon pea) |

| Common Name | Residue Definition | MRL (ppm)[1] | Food Commodity |
|---|---|---|---|
| | | 0.04 | Dried shelled pea and bean, except soybean (crop subgroup 6C); succulent shelled pea and bean (crop subgroup 6B) |
| | | 0.01 | Fat, meat and meat byproducts of cattle, goats, hogs horses, and sheep; milk. |

[1] ppm = parts per million
[2] The proposed MRL of 10 ppm for CG 13-07E will replace the currently established MRL of 3.0 for gooseberries.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

**International Situation and Trade Implications**

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the crop field trials used to generate residue chemistry data. For livestock commodities, differences in MRLs can also be due to different livestock feed items and practices.

Table 2 compares the MRLs proposed for isofetamid in Canada with corresponding American tolerances and Codex MRLs.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food and Feed website, by pesticide or commodity.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

**Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)**

| Food Commodity | Canadian MRL (ppm) | American Tolerance (ppm) | Codex MRL (ppm) |
|---|---|---|---|
| Small fruits vine climbing, except grape (crop subgroup 13-07E) | 10 | Not Established | Not Established |
| Bushberries (crop subgroup 13-07B) | 5.0 | 5.0[1] | Not Established |
| Caneberries (Crop subgroup 13-07A) | 4.0 | 4.0[1] | Not Established |
| Cherries (crop subgroup 12-09A); peaches (crop subgroup 12-09B) | 4.0 | Not Established | Not Established |
| Dried prune plums | 1.5 | Not Established | Not Established |
| Plums (crop subgroup 12-09C) | 0.8 | Not Established | Not Established |
| Apples; edible-podded legume vegetables (crop subgroup 6A, except pea (Pisum spp.), includes dwarf pea, edible-podded pea, snow pea, sugar snap pea, and pigeon pea) | 0.6 | Not Established | Not Established |
| Dried shelled pea and bean, except soybean (crop subgroup 6C), succulent shelled pea and bean (crop subgroup 6B) | 0.04 | Not Established | Not Established |
| Fat, meat and meat byproducts of cattle, goats, horses, hogs, and sheep; milk. | 0.01 | Not Established | Not Established |

[1] Time-limited tolerances, which will expire in 31 December 2019.

**Next Steps**

The PMRA invites the public to submit written comments on the proposed MRLs for isofetamid up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

# Appendix I

## Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data for isofetamid in various crops were submitted to support the domestic use of isofetamid on raspberry, blueberry, kiwifruit, cherries (sweet and tart), peach, plum, apple, beans and peas (both dry and succulent). In addition, processing studies in treated apples and plums were reviewed to determine the potential for concentration of residues of isofetamid into processed commodities.

## Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for isofetamid was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for various crops.

**Table A1 Summary of Field Trial and Processing Data Used to Support MRLs**

| Commodity | Application Method/ Total Application Rate (g a.i./ha)[1] | Preharvest Interval (days) | Lowest Average Field Trial Residues (ppm) | Highest Average Field Trial Residues (ppm) | Experimental Processing Factor |
|---|---|---|---|---|---|
| Blueberries | Foliar broadcast/ 1774-1957 | 6-8 | 0.184 | 3.59 | - |
| Raspberries | Foliar broadcast/ 1904-1954 | 6-7 | 0.202 | 1.59 | - |
| Kiwifruits | Foliar broadcast/ 1921-1957 | 7 | <0.01 | 3.8 | - |
| Cherries (sweet and tart) | Foliar broadcast/ 1063-1102 | 0-1 | 0.310 | 2.52 | - |
| Peaches | Foliar broadcast/ 1074-1130 | 1 | 0.240 | 1.70 | - |
| Plums | Foliar broadcast/ 1080-1106 | 1 | 0.030 | 0.360 | Prune: 4.0× |
| Apples | Foliar broadcast/ 1901-2905 | 18-21 | 0.020 | 0.380 | Juice: 0.3× |
| Snap beans (edible-podded) | Foliar broadcast/ 974-1034 | 5-7 | 0.031 | 0.325 | - |
| Green peas (succulent shelled) | Foliar broadcast/ 970-1004 | 2-17 | <0.01 | 0.025 | - |
| Lima beans (succulent shelled) | Foliar broadcast/ 986-1009 | 14 | <0.01 | <0.01 | - |
| Dry pea seeds | Foliar broadcast/ 966-1009 | 21-42 | <0.01 | 0.025 | - |
| Dry bean seeds | Foliar broadcast/ 811-1034 | 23-57 | <0.01 | 0.036 | - |

[1] g a.i./ha = grams of active ingredient per hectare

Based on the dietary burden and dairy cattle feeding study, MRLs of 0.01 ppm in milk, fat, meat and meat byproducts of cattle, goats, hogs, horses, and sheep, to cover residues of isofetamid are also proposed.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of isofetamid. Residues of isofetamid in these crop/livestock commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.